

REMARKS

Claims 11, 14-18, 22, 26-38, 41-42, 44-60 and 62-63 are in the application. Claims 20-21, 25, 28, 35-36, 52-58, 64-66 and 70-72 are withdrawn by the Office. Solely to compact prosecution, and without prejudice or disclaimer, claims 1-10, 12-13, 19-21, 23-25, 39-40, 43, 61 and 64-72 are cancelled. Solely to compact prosecution, and without prejudice or disclaimer, claims 11, 14-18, 22, 26-37, 41-42, 45, 59-60 and 62-63 are amended. Support for the Amendment is found, *inter alia*, in the Sequence Listing and at pages 16-22 of the specification. No new matter is added. Entry and consideration of the Amendment is respectfully requested.

Applicants thank the Examiner for acknowledging the Information Disclosure Statement of December 12, 2008.

I. Request for Rejoinder

Applicants request rejoinder of the withdrawn claims (i.e., claims 28-29, 35-36 and 57-58).

II. Applicants' Rights to All Non-elected and Cancelled Subject Matter Are Reserved

At page 2 of the Office Action, the Office imposes a Restriction Requirement alleging that there would be a "serious burden" on the Office to consider the withdrawn claims. Applicants disagree. Applicants explicitly reserve the right to all non-elected and cancelled subject matter in the present and any subsequently filed application.

III. Priority is Proper

At page 7 of the Office Action, the Office asserts that Applicants claim to priority is improper because the claims allegedly lack enablement and written description.

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Application No. 10/729,441 (A8689)

Applicants disagree. Solely to compact prosecution, and without prejudice or disclaimer, Applicants amend the claims thereby overcoming the rejections for lack enablement and written description (see *infra*). Applicants' Amendment renders moot the denial of priority.

Acknowledgement of priority is requested.

IV. No New Matter is Added

At page 9 of the Office Action, the Office alleges that Applicants' Amendment of April 16, 2007 adds "new matter" to the specification allegedly because disclosure was improperly incorporated by reference.

Applicants disagree and herewith reiterate and apply the arguments of record (e.g., in the Amendment Under 37 C.F.R. § 1.111, December 8, 2008). However, solely to compact prosecution, and without prejudice or disclaimer, Applicants herewith amend the claims. Applicants' Amendment overcomes the objection.

Withdrawal of the objection is requested.

V. The Claims Are Described Under 35 U.S.C. § 112, First Paragraph

At page 12 and 17 of the Office Action, the Office rejects claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37, 39-43, 59-60 and 62 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement; and claims 17, 30, and 32-34 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement because disclosure was improperly incorporated by reference, respectively.

Applicants disagree with the Office and maintain and apply the arguments of record, *inter alia*, in the Amendment of December 12, 2008. The rejection is moot as to claims 8, 19, 24, 39-40 and 43. Solely to compact prosecution, and without prejudice or disclaimer, Applicants herewith amend the claims. Applicants' Amendment overcomes the rejection.

Withdrawal of the rejection is requested.

VI. The Claims Are Enabled Under 35 U.S.C. § 112, First Paragraph

At page 20 of the Office Action, the Office rejects claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37, 39-43, 59-60 and 62 under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. At page 20 of the Office Action, the Office admits that the claims are enabled for a composition comprising an antibody or antigen binding fragment thereof that specifically binds to IGF-I-R, wherein said antibody or fragment comprises HC CDR1 SEQ ID NO:1, HC CDR2 SEQ ID NO:2, HC CDR3 SEQ ID NO:3, LC CDR1 SEQ ID NO:4, LC CDR2 SEQ ID NO:5, LC CDR3 SEQ ID NO:6.

Applicants disagree with the Office and maintain and apply the arguments made of record, *inter alia*, in the Amendment of December 12, 2008. The rejection is moot as to claims 8, 19, 24, 39-40 and 43. Solely to compact prosecution, and without prejudice or disclaimer, Applicants herewith amend the claims. Applicants' Amendment overcomes the rejection.

Withdrawal of the rejection is requested.

VII. The Claims Are Patentable Under 35 U.S.C. § 101

At page 24 of the Office Action, the Office rejects claims 8, 11, 14-19, 22, 24, 26, 27, 30-34, 37-44, 46-51, 59-63 and 67-69 on the grounds of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-22 of U.S. Patent No. 7,538,195 in view of Teicher et al. At page 26 of the Office Action, the Office rejects claim 45 under 35 U.S.C. § 101 as allegedly claiming the same invention as claimed in claim 8 of U.S. Patent No. 7,538,195. A similar allegation was made in the application that matured into US Patent No. 7,538,195 but the allegation was voluntarily withdrawn by the Office.

Applicants disagree with the Office. The rejection is moot as to claims 8, 19, 24, 39-40 and 43.

The subject matter of the present application is patentably distinct from the subject matter recited in the claims of the '195 Patent. The Office failed to appreciate Applicants' teachings, "the combined administration of EM164 antibody with taxol was significantly more inhibitory to the growth and survival of non-small cell lung cancer Calu6 cells than was taxol alone. Similarly, the combination of EM164 antibody with camptothecin was significantly more inhibitory than camptothecin alone toward the growth and survival of colon cancer HT29 cells. Because EM164 antibody alone was not expected to be as toxic to cells as organic chemotoxic drugs, the synergism between the predominantly cytostatic effect of EM164 antibody and the cytotoxic effect of the chemotoxic drug may be highly efficacious in combination cancer therapies in clinical settings." See, e.g., paragraph 145, specification.

Withdrawal of the rejection is requested.

VIII. The Objection to Claims 68 and 69 Is Moot

At page 25 of the Office Action, the Office objects to claims 68 and 69 as allegedly being drawn to a non-elected invention and for grammar.

Solely to compact prosecution, and without prejudice or disclaimer, Applicants herewith cancel the claims. The objection is moot.

Withdrawal of the objection is requested.

IX. Claim 59 Is Definite Under 35 U.S.C. § 112, Second Paragraph

At page 25 of the Office Action, the Office rejects claim 59 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Application No. 10/729,441 (A8689)

Solely to compact prosecution, and without prejudice or disclaimer, Applicants herewith amend claim 59. Applicants' Amendment overcomes the rejection.

Withdrawal of the rejection is requested.

CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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